

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

# PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

To:

Fish & Richardson P.C.  
Attn. Shippides, Geoffrey P.  
P.O. Box 1022  
Minneapolis MN 55440-1022  
ETATS-UNIS D'AMERIQUE

(PCT Rule 44.1)

Date of mailing  
(day/month/year)

12/01/2010

Applicant's or agent's file reference

10527-830W01

**FOR FURTHER ACTION**

See paragraphs 1 and 4 below

International application No.

PCT/US2008/069544

International filing date  
(day/month/year)

09/07/2008

Applicant

BOSTON SCIENTIFIC SCIMED, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

**For more detailed instructions,** see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.  
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

**4. Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

**Within 19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Joëlle Gerber

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annex B).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, International Phase, paragraph 296).

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet or sheets containing a complete set of claims in replacement of all the claims previously filed must be submitted.

Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively in Arabic numerals (Section 205(a)).

**The amendments must be made in the language in which the international application is to be published.**

#### What documents must/may accompany the amendments?

##### **Letter (Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annex B).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, International Phase, paragraph 296).

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet or sheets containing a complete set of claims in replacement of all the claims previously filed must be submitted.

Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively in Arabic numerals (Section 205(a)).

**The amendments must be made in the language in which the international application is to be published.**

#### What documents must/may accompany the amendments?

##### **Letter (Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|   |   |   |
|---|---|---|
| Applicant's or agent's file reference<br><br>10527-830W01 | <b>FOR FURTHER ACTION</b> <div style="float: right; font-size: small;">see Form PCT/ISA/220<br/>as well as, where applicable, item 5 below.</div> |   |
| International application No.<br><br>PCT/US2008/069544    | International filing date (day/month/year)<br><br>09/07/2008  | (Earliest) Priority Date (day/month/year)<br><br>13/07/2007 |
| Applicant<br><br>BOSTON SCIENTIFIC SCIMED, INC.           |   |   |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1
- ☒ as suggested by the applicant
- ☐ as selected by this Authority, because the applicant failed to suggest a figure
- ☐ as selected by this Authority, because this figure better characterizes the invention
- b. ☐ none of the figures is to be published with the abstract

# INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/069544

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61L31/02 A61L31/14 A61L31/12 A61L31/18

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|-----------|---|-----------------------|
| X         | WO 2004/108021 A2 (SDGI HOLDINGS INC [US];<br>ISTEPHANOUS NAIM [US]; MARIK GREG C [US];<br>LESS) 16 December 2004 (2004-12-16)<br>page 4, line 21 - line 25<br>page 7, line 14 - line 24<br>page 20 - page 21<br>page 22, line 3 - line 7<br>page 23, line 11 - line 13 | 1-9,<br>22-33         |
| X         | US 2004/187980 A1 (JUNG JIN-WON [US] ET<br>AL) 30 September 2004 (2004-09-30)<br>page 4, paragraph 52 - paragraph 53<br>page 5, paragraph 64; claims  | 1-9, 22,<br>29-30     |
| A         | EP 1 685 861 A2 (GREATBATCH INC [US])<br>2 August 2006 (2006-08-02)<br>column 5, paragraph 39<br>column 6, paragraph 43; claims   | 1-33                  |
| -/--      |   |                       |

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

21 December 2009

Date of mailing of the international search report

12/01/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040.  
Fax: (+31-70) 340-3016

Authorized officer

Espinosa y Carretero

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/069544

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|-----------|---|-----------------------|
| A         | US 5 477 864 A (DAVIDSON JAMES A [US])<br>26 December 1995 (1995-12-26)<br>column 1, line 21 - line 25<br>column 11, line 60 - line 62<br>column 14, line 10 - line 50; claims<br>-----   | 1-33                  |
| A         | US 2007/137734 A1 (PAWAR VIVEK [US] ET AL)<br>21 June 2007 (2007-06-21)<br>page 8, paragraph 54 - paragraph 60<br>-----   | 1-33                  |
| A         | WO 2007/024537 A1 (BOSTON SCIENT SCIMED<br>INC [US]; STINSON JONATHAN S [US])<br>1 March 2007 (2007-03-01)<br>claims<br>-----   | 1-33                  |
| A         | RIBEIRO R ET AL: "Tribological<br>characteristics of boronized niobium for<br>biojoint applications"<br>VACUUM, PERGAMON PRESS, GB,<br>vol. 80, no. 11-12,<br>7 September 2006 (2006-09-07), pages<br>1341-1345, XP025009628<br>ISSN: 0042-207X<br>[retrieved on 2006-09-07]<br>abstract<br>-----       | 1-33                  |
| A         | YANG W S ET AL: "Ductilization of<br>Ti-Ni-Pd shape memory alloys with boron<br>additions"<br>SCRIPTA METALLURGICA ET MATERIALIA,<br>OXFORD, GB,<br>vol. 28, no. 2,<br>15 January 1993 (1993-01-15), pages<br>161-165, XP024182201<br>ISSN: 0956-716X<br>[retrieved on 1993-01-15]<br>abstract<br>----- | 1-33                  |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/069544

| Patent document<br>cited in search report |    | Publication<br>date |      | Patent family<br>member(s) |  | Publication<br>date |
|---|----|---------------------|------|----------------------------|--|---------------------|
| WO 2004108021                             | A2 | 16-12-2004          | AU   | 2004245008 A1              |  | 16-12-2004          |
|   |    |                     | CA   | 2527327 A1                 |  | 16-12-2004          |
|   |    |                     | CN   | 1816309 A                  |  | 09-08-2006          |
|   |    |                     | EP   | 1631220 A2                 |  | 08-03-2006          |
|   |    |                     | JP   | 2006528540 T               |  | 21-12-2006          |
|   |    |                     | KR   | 20060028634 A              |  | 30-03-2006          |
| US 2004187980                             | A1 | 30-09-2004          | EP   | 1629134 A2                 |  | 01-03-2006          |
|   |    |                     | WO   | 2005111255 A2              |  | 24-11-2005          |
| EP 1685861                                | A2 | 02-08-2006          | NONE |                            |  |                     |
| US 5477864                                | A  | 26-12-1995          | US   | 5573401 A                  |  | 12-11-1996          |
|   |    |                     | US   | 5545227 A                  |  | 13-08-1996          |
| US 2007137734                             | A1 | 21-06-2007          | AU   | 2006333519 A1              |  | 12-07-2007          |
|   |    |                     | CA   | 2633096 A1                 |  | 12-07-2007          |
|   |    |                     | CN   | 101374479 A                |  | 25-02-2009          |
|   |    |                     | EP   | 1968493 A2                 |  | 17-09-2008          |
|   |    |                     | JP   | 2009519750 T               |  | 21-05-2009          |
|   |    |                     | US   | 2008289729 A1              |  | 27-11-2008          |
|   |    |                     | US   | 2009074836 A1              |  | 19-03-2009          |
|   |    |                     | WO   | 2007078427 A2              |  | 12-07-2007          |
| WO 2007024537                             | A1 | 01-03-2007          | CA   | 2620169 A1                 |  | 01-03-2007          |
|   |    |                     | EP   | 1934381 A1                 |  | 25-06-2008          |
|   |    |                     | JP   | 2009505728 T               |  | 12-02-2009          |
|   |    |                     | US   | 2007044871 A1              |  | 01-03-2007          |
|   |    |                     | US   | 2009222079 A1              |  | 03-09-2009          |

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:

see form PCT/ISA/220

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2008/069544

International filing date (day/month/year)  
09.07.2008

Priority date (day/month/year)  
13.07.2007

International Patent Classification (IPC) or both national classification and IPC  
INV. A61L31/02 A61L31/14 A61L31/12 A61L31/18

Applicant  
BOSTON SCIENTIFIC SCIMED, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office  
P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk - Pays Bas  
Tel. +31 70 340 - 2040  
Fax: +31 70 340 - 3016

Date of completion of  
this opinion

see form  
PCT/ISA/210

Authorized Officer

Espinosa y Carretero

Telephone No. +31 70 340-2771





**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2008/069544

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**Box No. I    Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2008/069544

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

|                               |             |                   |
|-------------------------------|-------------|-------------------|
| Novelty (N)                   | Yes: Claims | <u>10-21</u>      |
|                               | No: Claims  | <u>1-9, 22-33</u> |
| Inventive step (IS)           | Yes: Claims |                   |
|                               | No: Claims  | <u>1-33</u>       |
| Industrial applicability (IA) | Yes: Claims | <u>1-33</u>       |
|                               | No: Claims  |                   |

2. Citations and explanations

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Cited documents**

Reference is made to the following documents:

- D1 WO 2004/108021 A2 (SDGI HOLDINGS INC [US]; ISTEPHANOUS NAIM [US]; MARIK GREG C [US]; LESS) 16 December 2004 (2004-12-16)
- D2 US 2004/187980 A1 (JUNG JIN-WON [US] ET AL) 30 September 2004 (2004-09-30)

**2. Novelty**

The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claims 1-9 and 22-33 is not new.

D1 discloses implantable medical devices such as stents, implantable tubes, catheter tips... (see page 7, line 14-24) at least partially formed from a metal matrix composite that provides a metal matrix and a reinforcing component interspersed within the metal matrix (see page 20, line 21-30). The reinforcing component includes metal borides such as  $TiB_2$  (see page 21, line 14-19).

Therefore, the subject-matter of claims 1-9, 22-33 is not new over D1 according to Article 33(2) PCT.

D2 discloses high-strength, low hysteresis shape memory alloys (SMAs) and, in particular TiNi-based SMAs, employing coherent low-misfit nanoscale size precipitates (see page 2, paragraph 13) which can be used in self-expanding medical stents (see page 5, paragraph 64). To improve ductility of the material the grain size has to be reduced, and for this purpose Boron is preferably added to form borides (see page 4, paragraph 52).

Therefore, the subject-matter of claims 1-9, 22, 29-30 is not new over D2 according to Article 33(2) PCT.

### **3. Inventive step**

The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claims 1-33 does not involve an inventive step.

As the subject-matter of claims 1-9 and 22-33 is not new it cannot be considered as involving an inventive step (Article 33(3) PCT).

D1 is regarded as being the closest prior art. It discloses implantable medical devices such as stents, implantable tubes, catheter tips... (see page 7, line 14-24) at least partially formed from a metal matrix composite that provides a metal matrix and a reinforcing component interspersed within the metal matrix (see page 20, line 21-30). The reinforcing component includes metal borides such as  $Ti B_2$  (see page 21, line 14-19).

The subject-matter of claims 10-21 therefore differs from this known D1 in the size of the boride intermetallic phases and in different physical properties of the alloy.

The problem to be solved by the present invention may therefore be regarded as the provision of alternative endoprosthesis with increased elastic modulus and better recoil performance.

The solution proposed in claims 10-21 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The features in claims 10-21 are merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

Thus, the subject-matter of claims 10-21 does not fulfill the requirements of Article 33 (3) PCT.

## Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

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### General information

For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.

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### Amending claims under Art. 19 PCT

Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.

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### Filing a demand for international preliminary examination

In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).

If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).

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### Filing informal comments

After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.

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### End of the international phase

At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).

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### Relevant PCT Rules and more information

Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003

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